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EXHIBIT 2
510(k) Summary

PANORAMIC CORP.
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December 14, 2004

Contact: Doug Pack, Director of Operations.

1. Identification of the Device:
   Proprietary-Trade Name: Model PC-1000 Panoramic / Cephalometric X-ray Systems
   Classification Name: Unit, x-ray, extraoral with timer
   Product Code: EHD
   Common/Usual Name: Panoramic Dental X-Ray System

2. Equivalent legally marketed devices: Model PC-1000 Panoramic / Cephalometric X-ray System K882436

3. Indications for Use (intended use) For diagnostic radiographic use in dental, oral surgery, and orthodontic practices.

4. Description of the Device: The PC-1000 panoramic X-ray machine provides a panoramic picture, showing 70-80% more anatomy than a standard series of full-mouth X-rays. Inscribed lines and an angled mirror aid in accurately establishing the Frankfort plane and the midsagittal plane. In addition, the numbered temple supports allow accurate measurement of skull density for proper kVp settings, eliminating the guess work typical in panoramic radiography. Panoramic's quick and easy installation allows more time to be spent on demonstration. As your new Panoramic X-ray is installed, our service representative will test and calibrate the equipment, as well as teach your personnel how to use it. Panoramic provides you with a professional operator's manual in both print and on video tape so you can teach new personnel the operation of the PC-1000 as well as refresh the memory of your current staff. Each free-standing PC-1000 is shipped and delivered almost completely assembled, avoiding the noise and hours of disruption that is common with unassembled models. Also, the PC-1000 plugs into a standard 115-volt outlet eliminating the need for expensive rewiring or modifications to one's office.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

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6. Substantial Equivalence Chart, Model PC-1000 Panoramic / Cephalometric X-ray Systems

Characteristic	Model PC-1000 Panoramic / Cephalometric X-ray Systems K882436	Modified Model PC-1000 Panoramic / Cephalometric X-ray Systems
Intended Use:	Diagnostic Dental X-Rays (Panoramic and Cephalometric)	SAME
Energy Source:	120 V Ac 20 A	SAME
User Interface	Dedicated Controls	Touch Controls
Maximum output	90 kVp	SAME
Focal spot	0.5 mm x 0.5 mm	SAME
Tube Current	6 ma	SAME
Exposure time	12 seconds	SAME
Method of Control	Analog Hardware	(3) Microprocessors
Performance Standard	Complies with 21 CFR Part 1020.	SAME
International Standards	IEC 60601-1 (1988-12) & amend. IEC 60601-2-7 IEC 60601-2-28, IEC 60601-1-2	SAME
Safety	UL Listing	SAME

7. Conclusion

After analyzing bench, user, and standards testing data, it is the conclusion of Panoramic Corporation that the Model PC-1000 Panoramic / Cephalometric X-ray Systems are as safe and effective as the predicate device, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Panoramic Corp.
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K043557
Trade/Device Name: Model PC-1000 Panoramic/ Cephalometric X-ray Systems
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: December 24, 2004
Received: December 27, 2004

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043557

Device Name: Model PC-1000 Panoramic / Cephalometric X-ray Systems . (Modification to K882436)

Indications For Use:
For diagnostic radiographic use in dental, oral surgery, and orthodontic practices.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043557